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## 1. WELCOME

### **Thank you for purchasing the Valkee® bright light headset!**

Your Valkee sales package contains the following accessories and materials:

- A USB cable
- A bag of silicone fittings
- Instructions for use (quick guide, user guide and technical information)

**This user guide contains important information about the appropriate use of your Valkee device.**

Read all safety information and instructions for use carefully before using the device.

### **KEEP THE USER GUIDE FOR FUTURE REFERENCE.**

Visit *[www.valkee.com/support](http://www.valkee.com/support)* now to:

- Register your device, to benefit fully from Valkee user support
- Learn more about your device

Please send us your feedback at *[support@valkee.com](mailto:support@valkee.com)* or share it on Facebook at *[facebook.com/ValkeeCompany](https://facebook.com/ValkeeCompany)*.

## **1.1. INTENDED USE**

The Valkee 2 bright light headset is intended for use to treat symptoms of seasonal affective disorder. It can also be used to promote adjustment to ambient time, and aid in improving your energy level, reaction time, and attention.

For treatment of symptoms of seasonal affective disorder, the device is considered a Class II(a) medical device under Directive 93/42/EEC and has been CE marked and clinically tested. For promoting adjustment to ambient time, and aiding in improving your energy level, reaction time, and attention, the device is not considered a Class II(a) medical device as defined in Directive 93/42/EEC.

## 1.2. SAFETY INFORMATION

**IMPORTANT NOTE:** Use the device only as instructed by Valkee, to avoid potential personal injury or damage to the device. Read all warnings and cautions before using the device.



The device has CE Class II(a) medical device certification and has been clinically tested. The device meets the requirements of the Medical Device Directive 93/42/EEC.

**CONTRAINDICATIONS:** The device is not intended for children or for use during pregnancy.

The device may not be suitable for individuals who are on photo-sensitising medications or who suffer from bipolar disorder.

Side effects of use of the device are rare when the instructions for appropriate use are followed. The most common side effects are temporary headache on the first days of usage, insomnia, restlessness, and decreased quality of sleep or sleeplessness during the early morning hours.



**WARNINGS:** Consult your physician and have your current medication reviewed before using the device, if:

- You have low blood pressure

(hypotension)

- You have an ear infection
- You suffer from, or have suffered from, depression
- You have bipolar disorder
- You are hypersensitive to light (e.g. because of epilepsy)
- You are taking:
  - e.g. certain antibiotics or herbal compounds such as hypericin
  - antidepressants (e.g., neuroleptics or monoamine oxidase inhibitors, or psychotropic drugs)
  - anti-malarial tablets

**DO NOT** use the device while performing tasks that require unrestricted hearing, to avoid hazards due to restriction in hearing capability caused by the earplugs.

**DO NOT** look directly into the light-emitting earplugs, to avoid eye irritation or damage.

**DO NOT** use excessive force to insert the earplugs, to avoid damaging your ear canals.

**KEEP THE DEVICE** and its parts out of the reach of children. The small parts could present a choking hazard.

**IF THE DEVICE** becomes damaged or degraded in any way or does not work, do not oper-

ate it. Contact Valkee for service assistance.

**DO NOT** share earplugs to avoid personal hygiene risks.

**DO NOT** overuse the device. This helps avoid nausea, headache and sleep disturbances. No clinical data are available on side effects of multiple dosing.

**MAKE SURE** that neither the device nor any of its cables can catch on anything when you are using the device, to eliminate the possibility of strangulation.



**CAUTIONS:** For safe operation, keep the device away from water. If liq-

uid has somehow entered the system or its parts, immediately stop using the device and contact Valkee for service assistance.

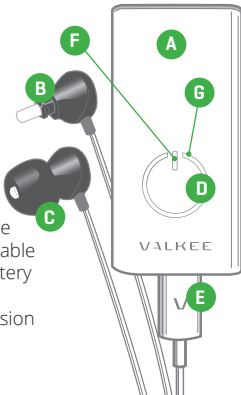
The device contains an integrated, rechargeable lithium-ion battery. Do not incinerate, disassemble, or expose to extreme temperatures, because the battery could overheat, causing fire or bursting.

Other electrical equipment may affect this device; Use the device in accordance with the guidelines for electromagnetic compatibility (EMC) as described in the EMC information leaflet contained in the sales package.

No modification of this device is allowed. Contact Valkee for service assistance.

## 1.3. PRODUCT DESCRIPTION

- A.** Valkee main unit
- B.** Ledset earplugs
- C.** Silicone fitting for the earplug
- D.** Power on/off button
- E.** USB connector for the Ledset and charger cable
- F.** Indicator light for battery power and charging
- G.** Indicator light for session length and progress



### SYMBOL KEY:

	Follow the instructions for use
<b>S/N</b>	Serial number
	European Declaration of Conformity
	Keep dry
	Compliant with the Waste Electrical and Electronic Equipment and Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (WEEE) recycling directives (2012/19/EU and 2006/66/EC)

## 1.4. LIGHT AND HEALTH

Our daily functioning varies in line with the 24 hours of the day. This circadian (from circa = about, dies = day) variation is caused by our internal biological clock, which gets its timing cues from the external light-dark cycle. A well-synchronized biological clock helps regulate our mood, sleep, energy, appetite and digestion and helps ensure our well-being. Sometimes our internal clock gets out of sync with the external world, – for example, because of long-distance travel or working night shifts. This can cause various health-related problems.

Many factors in day-to-day life diminish the

ability of our internal biological clock to synchronise us properly with our external environment. We no longer work regularly from dawn to dusk: many people work irregular hours or must follow shift-work schedules, or travel extensively across several time zones. Also, modern electric lighting allows activities to extend well into the night.


These factors can be balanced through exposure to bright light that is timed with the individual's needs in mind. For more information about how to use the device to improve your well-being, visit [www.valkee.com/support](http://www.valkee.com/support).

## 2. USE OF THE DEVICE

The device emits UV-free, blue-enriched white light through the ear canals to the light-sensitive regions of the brain. Most people benefit from the default bright light settings of the device (see "Technical Information") when applied in the morning.

Good timing of exposure to Valkee bright light is essential for reaching the best results. The best time to use your device depends on the intended purpose of use. The most effective bright-light time also varies with the individual, so you will find the best bright-light time (morning/midday/evening) by experimenting.

### 2.1. BASIC USE

Your device is ready for use. Before the first use, select the silicone fittings that best match your ears and put them on the earplugs. Then connect the Ledset with the main unit. For illustrations, see the quick guide .

To use your device daily:

1. Place the earplugs carefully in your ear canals.
2. Start the session by briefly pressing and then releasing the power button.
3. Recharge the device if it does not start and repeat steps 1 and 2.



4. Enjoy the Valkee bright light until the device switches off automatically after 12 minutes (by default).
5. Clean the earplugs regularly.

**NOTE:** You can interrupt the session by pressing the power button again. If you turn on the device again within 10 seconds, you can resume the session from the point of interruption.

**NOTE:** If you press the power button to start the device without first connecting the Ledset, the device gives an error signal (four beeps and four flashes).

## 2.2. SUGGESTED USE

**GENERAL WELL-BEING:** To help improve your mood and cognitive performance, boost your daily energy levels and increase your general well-being, use the device whenever you feel you could benefit from it in the course of the day.

To alleviate typical symptoms of **SEASONAL AFFECTIVE DISORDER**, such as depression, anxiety, irritability, loss of interest in activities you usually find enjoyable, feeling of worthlessness, hopelessness, oversleeping, loss of energy, social

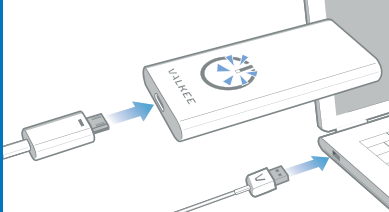
withdrawal, decreased physical activity, fatigue, cravings for foods that are high in carbohydrates, and weight gain, use the device on a regular basis **in the morning within two hours after waking up** at the same time each day.

If your seasonal mood swings are more severe and you are suffering from depression, or if you currently are on medication for depression, consult your physician and use light therapy only under supervision.

## 2.3. CHARGING

It is recommended to use the charger sold or otherwise provided by Valkee for your device. Other chargers or power sources may exceed the limits of IEC 60601-1. However, the device can also be charged with many mobile-phone chargers or smartphone micro-USB chargers or from a computer's USB port without damage to the device.

If you have a problem with charging, see the 'Troubleshooting' section.



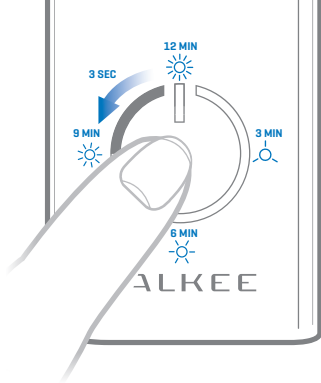
*Connect the USB cable to the main unit and the computer's USB port. Charging is in progress when the battery-indicator lights cycle on and off; the battery is fully charged when all the indicator lights are illuminated steadily. Recharge your device when the bottom-most indicator light is flashing.*

## 2.4. ADJUSTMENT OF THE LIGHT SETTINGS

Before you consider changing the default settings, try the bright light at a different time of day: not everyone benefits from morning light exposure. However, if you feel that the default settings don't benefit you or if you experience a negative side effect, such as a headache, you can change the light settings.

On first use, the session starts with the default bright-light settings (see “Technical Information”). The default settings can be adjusted in the following manner:

1. Turn off the device.
2. Press the power button for three seconds to reduce the length of the session by three minutes and the intensity of the bright light by 25%. For further reduction, continue holding down the power button.
3. If you want to return to the default settings, continue holding the power button down. The device saves your new settings to the Ledset.



## 2.5. TROUBLESHOOTING

**ERROR CONDITION :** The device gives an error signal (four beeps and four flashes of the indicator lights) if the Ledset becomes disconnected or broken. To rectify the error, make sure that the Ledset is properly connected to the main unit and/or that the Ledset earplugs and Ledset wires are not broken. If the error persists, contact Valkee.

## 2.6. MAINTENANCE AND SERVICE

See "Technical Information" for appropriate environments for operation, transportation and storage.

**CLEANING:** The device is intended for personal use only. Clean the earplugs and silicone fittings between uses with a non-abrasive, dry cleaning cloth. Never use abrasive cleaning agents or strong detergents to clean the device, and do not rinse it with water.

**STORAGE:** Store the device between uses or during potential idle periods in a protective case or bag in a dry location.

**SERVICE AND REPAIR:** Contact Valkee at [support@valkee.com](mailto:support@valkee.com) with any warranty, service or support issues.

### 3. DISPOSAL

This is an electronic device containing a lithium-ion battery as an internal power source. Do not throw away the device with normal household waste at the end of its life. Consider the environment: deliver the device for recycling at an official collection point for electronic devices. Check with the appropriate recycling organisation for local disposal information.

### 4. WARRANTY AND LEGAL INFORMATION

The limited Valkee warranty period of one year starts on the date of purchase.

Valkee is responsible for the device being suitable for its purpose of use and remaining usable throughout the warranty period. The warranty covers any material, design, and manufacturing defects that manifest themselves during the warranty period. This limited warranty does not cover:

- Normal wear and tear of the device or its components
- Cosmetic changes in the device
- Faults or damage caused by use or handling of the device in a manner that is incorrect, inappropriate, or counter to the operation and service instructions
- Faults or damage caused by the customer,

for example, from opening the device or repairing, adjusting, or modifying it

- Faults or damage caused by factors that Valkee cannot reasonably be expected to have control over

Faults must be reported within reasonable time from their detection. When reporting a fault, you must present a certificate of warranty, a receipt of purchase, or another reliable account of where and when the product was purchased.

Valkee or an authorised Valkee service point may choose to repair the fault or provide a replacement device. Opening, modifying or repairing the device at an unauthorised service point voids this limited warranty. This limited warranty

does not restrict application of any consumer-protection legislation in force.

Valkee liability is always limited to the purchase price of the device at maximum. Under no circumstances is Valkee liable for compensation for any incidental, indirect, or consequential damages unless legislative requirements impose an obligation of such compensation.

**COPYRIGHT:** These instructions are protected by the applicable copyright laws. Copying of these instructions, in full or in part, is permitted only with the written permission of Valkee. Valkee reserves the right to modify these instructions without prior notice.

## 5. TECHNICAL INFORMATION

**NOTE:** See the separate leaflet in the sales package for the EMC information.

**MODEL** VALKEE 2

### IEC 60601-1 CLASSIFICATION

Mode of operation Continuous

### DEVICE'S ELECTRICAL SPECIFICATIONS

Rated voltage 5 V (DC)  
Power consumption max. 0.5 A

### BATTERY SPECIFICATION

Lithium-ion battery 3.7 V, 450 mAh  
Battery recharging time max. 3 hours  
Battery operation with one charge 12 sessions  
Expected battery service life 3 years

### ADAPTER SPECIFICATIONS (OPTIONAL)

Rated input voltage 100–240 V (AC)

Rated frequency 50–60 Hz

### OPERATING CONDITIONS

Temperature from 5 °C to 40 °C  
Relative humidity 15–93% non-condensing

### TRANSPORT AND STORAGE CONDITIONS

Temperature from -25 °C to 70 °C  
Relative humidity no control at -25 °C, up to 93% non-condensing at 70 °C

### PHYSICAL CHARACTERISTICS

Dimensions 75 × 36 × 9 mm  
Expected device service life 3 years

### LIGHT FUNCTIONS

Typical session duration 12 min (default)  
Average light intensity >10 000 lux within 1 cm from the top of the light guide, 3.5 lumen (default values)  
Peak wavelength 450 nm